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Application Number	10/066,436
Filing Date	1/30/2002
First Named Inventor	Steve G. Baker
Art Unit	3738
Examiner Name	Thomas C. Barrett
Attorney Docket Number	ENDOV-59271

ENCLOSURES *(Check all that apply)*

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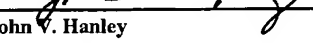
Signature			
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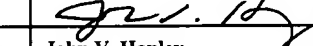
Signature			
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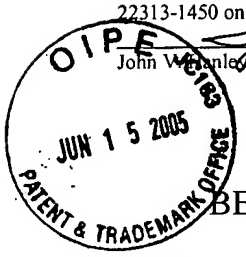


IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the application of	Examiner: Thomas C. Barrett
Inventor: Steve G. Baker, et al.	Group Art Unit: 3738
Serial No. 10/066,436	Client ID/Matter No. ENDOV-59271
Filed: January 30, 2002	June 6, 2005
For: THORACIC GRAFT AND DELIVERY SYSTEM	

SECOND SUPPLEMENTAL APPELLANT'S BRIEF (CFR § 1.192)

MS: Appeal Brief Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Second Supplemental Appellant's Brief is being filed in response to the Notice of Non Compliant Appeal Brief dated May 19, 2005. A Supplemental Appellant's Brief was previously filed in response to the Office action dated June 3, 2004. The fees required under § 1.17 were submitted on October 17, 2003. In the event additional fees are required, authorization is hereby provided to charge our Deposit Account No. 06-2425 any fees due in connection with this paper.

This brief contains items under the following headings, and in the order set forth below:

I. REAL PARTY IN INTEREST

The real party in interest in this appeal is the following party: EndoVascular Technologies, Inc., 3200 Lakeside Drive, Santa Clara, CA 95054, which is a wholly-owned subsidiary of Guidant Corporation, 111 Monument Circle, 29th Floor, Indianapolis, IN 46204-5129.

II. RELATED APPEALS AND INTERFERENCES

With respect to other appeals or interferences that will directly effect, or be directly effected by, or have a bearing on the Board's decision on this appeal, it is to be noted that is believed there are no such appeals or interferences known to the applicant.

III. STATUS OF CLAIMS

The status of the claims in this application are:

A. Total Number of Claims in the Application

The claims in the application are: Claims 22-32

B. Status of All of the Claims

Each of pending claims 22-32 stand as finally rejected under 35 U.S.C. § 103(a).

C. Claims on Appeals

The claims on appeal are each of pending claims 22-32.

IV. STATUS OF AMENDMENTS

On June 17, 2003, claims 22-24, 27 and 30-32 were finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Lazarus et al. (U.S. 5,275,622; Exhibit A) in view of Rhodes (U.S. 5,122,154; Exhibit B). Additionally, claims 22, 25, 26, 28 and 29 were finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus et al.

In response thereto, the Applicants filed a paper dated August 18, 2003 arguing for the allowance of the pending claims. Subsequently, the Examiner issued an Advisory Action on August 29, 2003. The August 2003 Advisory Action indicated that the Examiner did not believe that Applicants' arguments were persuasive.

After filing an Appeal Brief on December 17, 2003 and a second Appeal Brief on February 17, 2004 in response to a Notification of Non-Compliance, prosecution was re-opened and an Office action was issued on June 3, 2004. In the June 3, 2004 Office action, claims 22-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable with Rhodes (U.S. 5,122,154) in view of Lazarus et al. (5,275,622). The previous rejection under § 103(a) based on the Lazarus et al. patent in view of the Rhodes patent was apparently traversed by the Applicants' arguments submitted in the earlier filed Appeal Brief.

V. SUMMARY OF CLAIMED INVENTION

As recited in independent claim 22, and as set forth in the specification of the present application, the recited graft assembly is contemplated to be configured for repairing a diseased condition of vasculature such as an aneurysm (p. 4, lns. 4-12; p. 35, lns. 29-32).

Moreover, as recited in independent claim 22, the graft assembly includes a graft having a length, a first end and a second end (p. 32, ln. 14 et seq.). A plurality of unconnected and discrete frames are attached to the graft substantially along the length of the graft (FIG. 25; reference characters 55, 175, 176; p. 26, lns. 17-20). Each frame defines a ring and includes a plurality of alternating apices (See generally p. 26, ln. 13 et seq.). Significantly, the frames can be self-expanding (See generally FIGS. 36-41; p. 25, lns. 18-33; p. 27, ln. 34 et seq.).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 22-32 were improperly rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus et al.

VII. ARGUMENT

A. Overview

A tenet which is highly significant to the prosecution of the present application is set forth in MPEP Section 2143.03. That is, to "establish prima facie obviousness of a claimed invention, all claim limitations must be taught or suggested by the prior art." In re Rozka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Additionally, it is submitted that as is supported by MPEP Section 2144, by mischaracterizing the cited art, the Examiner has not presented a convincing line of reasoning supporting the rejection of the claims. Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter.

1985). Since the art appears to lack the teaching of the limitations recited in the claims, should the rejections be based upon facts within the personal knowledge of the Examiner, the data supporting that knowledge should be stated as specifically as possible and the facts relied upon must be supported. (See MPEP Section 2144.03 and 37 CFR 1.104(d)(2)).

Significantly, the Court of Appeals for the Federal Circuit in In re Lee, 61 USPQ 21 1430 (Fed. Cir. 2002) reinforced the obligation of a fact finder to develop evidentiary bases for conclusions concerning the application of art to claims. As to certain limitations recited in each of the pending claims, it is respectfully submitted that no evidentiary basis has been provided for the combination of the cited art and in fact, the cited art teaches away from each other.

B. Group I: Claims 22-32

1. Lazarus et al. in view of Rhodes

Claims 22-32 have been finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Rhodes in view of Lazarus et al. In rejecting the claims in the June 3, 2004 Office action, the Examiner stated that "It would have been obvious to one of ordinary skill in the art to combine the teachings of self-expanding frames, as taught by Lazarus et al., to a graft as per Rhodes, in order to yieldably urge the graft from a compressed condition to a second expanded condition." Moreover, in response to arguments by the Applicants to the contrary, the Examiner stated that: "The Rhodes reference would not require a substantial reconstruction and redesign of elements shown in the <sic> as well as a change in the basic principle under which the construction was designed to operate. For example, a self-expanding stent can still be expanded with a balloon and the device would still function as an endovascular bypass graft. Rhodes states that the method of use of the graft entails introducing it by utilizing 'some means, e.g., disposing the sleeve on a conventional balloon catheter.' This implies that other means are possible even through a balloon catheter is preferred."

It is to be recognized that MPEP 2145 while referencing MPEP 2143.01, states that there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine referenced teachings. It is additionally noted that MPEP 2143.01 states that "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Additionally, "A statement that modifications of the prior art to meet the claimed invention would have been 'well within the ordinary skill in the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facia* case of obviousness without some objective reason to combine the teachings of the references." Further, the MPEP states that "The level of skill in the art cannot be relied upon to provide the suggestion or to combine references."

It is respectfully submitted that combining the Rhodes and Lazarus et al. references under § 103 is improper because there is no suggestion or motivation, nor an objective reason for the combination. It is particularly improper here since Rhodes is concerned with avoiding the shortcomings of self-expanding structures and specifically teaches a stent formed from rigid links or struts (Col. 6, ln. 33). The combination of teachings employed in the final Office action requires Rhodes to be modified to incorporate a self-expanding frame which is, in fact, the very characteristic Rhodes seeks to avoid.

Notably, the Rhodes patent is concerned with limiting perceived shortcomings associated with self-expanding stent devices (See Col. 2, lns. 30 et seq.). Rhodes teaches that zig-zag stainless steel wire stents are lacking because the expansion thereof is dependent upon a spring constant and the modules of elasticity of the structure, the same resulting in the possibility of the

size of the device changing after implantation. This structure was also said to be problematic in that an undersized structure may not expand sufficiently and become impacted in the arterial wall, thus permitting migration. Moreover, an oversized structure was characterized in the Rhodes reference as being capable of causing a rupture or tear in the vasculature. The Rhodes reference therefore, teaches employing a balloon expandable stent structure formed from rigid struts and consequently, actually teaches away from a self-expanding device.

Accordingly, it is respectfully submitted that the reason given by the Examiner for the combination of the Rhodes reference and the Lazarus et al. reference is flawed. One of ordinary skill in the art would not read the cautions regarding self-expanding structure set forth in Rhodes and then conclude that such structure should be added to the Rhodes graft device.

To wit, it is submitted that one of ordinary skill in the art would not as suggested by the Examiner, combine Rhodes with the teachings of Lazarus et al. in order to provide the Rhodes graft with structure "to yieldably urge the graft from a compressed position to a second expanded condition." It is in fact the "yieldable urging" characteristic of a self-expanding stent that according to Rhodes, leads to the undesirable possibility of the size of the device changing after implantation or the device becoming an oversized structure capable of causing a rupture or tear in vasculature.

It is also believed to be highly significant to the rejection of Group I claims 22-32 that MPEP 2143.01 additionally states that "If the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facia* obvious."

In this regard, it is believed to be relevant that the In re Ratti (270 F.2d 810; 123 USPQ 349 (CCPA 1959)) case cited in the MPEP for this proposition involved reviewing a rejection of

claims based upon the combination of a primary reference that disclosed a device requiring rigidity for operation and a secondary reference that taught spring fingers biased radially to urge structure outwardly. In reversing the rejection, the court stated that the primary reference "points away from the addition of any spring element" and further held that the "suggested combination of references would require a substantial reconstruction and redesign of elements shown in the [primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate."

Here, the basic principle under which the graft device in Rhodes was designed to operate relates to a device having stent structure which is controllably expanded by a balloon catheter so as to avoid the possibility of the stent structure changing after implantation, being undersized and ultimately migrating within vasculature and/or being oversized and causing a rupture or tear in vasculature. Substituting the balloon expanded stent structure of Rhodes with a self-expanding stent structure would indeed change the principle operation of the Rhodes graft device since as taught by Rhodes, the resultant device could for example cause a rupture by continuing to expand after implantation.

It is respectfully submitted that the Examiner's statement that a self-expanding stent can be expanded with a balloon and still function as an endovascular graft is an over-reaching attempt to characterize the teachings and principle operation of Rhodes to meet the subject matter recited in claims 22-32. Using the Examiner's logic, any feature of a particular device can be added to the Rhodes graft to meet subject matter recited in the claims so long as the resultant device functions as an endovascular graft. That is, if it is proper to modify the Rhodes device to include the very structure (self-expanding stent) which Rhodes seeks to avoid, it must follow that

virtually any modification of Rhodes is permissible. Clearly, this cannot be proper under § 103(a).

Therefore, we are left without a motivation or suggestion to combine the Rhodes and Lazarus et al. references as well as without an objective reason for the combination. Add to that changing the principle operation of the Rhodes device, the conclusion can only be that a *prima facia* case of obviousness has not been made.

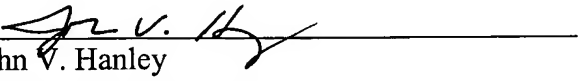
Thus, it is respectfully submitted that the combination of Rhodes and Lazarus et al. to reject claims 22-32 was made in error.

CONCLUSION

For all the reasons stated above, Applicant respectfully submits that the Examiner has erred in rejecting claims 22-32. It is respectfully requested that the Board reverse the rejection of claims 22-32 and allow claims 22-32 to issue.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: 
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VIII. CLAIMS

Claim 22 (previously presented): A graft assembly for repairing aneurysms, comprising:

a graft having a length, a first end and a second end; and

a plurality of unconnected and discrete frames attached to the graft along substantially the length of the graft, each frame defining a ring and having a plurality of alternating apices and at least one of the plurality of frames being self-expanding.

Claim 23 (previously presented): A graft assembly of claim 22, further comprising at least one wall engaging member attached to one of the plurality of frames.

Claim 24 (previously presented): A graft assembly of claim 23, wherein the wall engaging member is in the form of a hook.

Claim 25 (previously presented): The graft assembly of claim 22, wherein each of the plurality of frames are self-expanding.

Claim 26 (previously presented): The graft assembly of claim 22, further comprising a helix configured at each of the alternating apices.

Claim 27 (previously presented): The graft assembly of claim 22, further comprising a plurality of wall engaging members attached to one of the plurality of frames.

Claim 28 (previously presented): The graft assembly of claim 22, wherein the graft assembly has a tapered profile.

Claim 29 (previously presented): The graft assembly of claim 28, further comprising a longitudinal pleat which provides the graft assembly with a tapered profile.

Claim 30 (previously presented): The graft assembly of claim 22, wherein each of the plurality of frames have a length, each of the frames being configured so as to lack structure overlapping the length of an adjacent frame.

Claim 31 (previously presented): The graft assembly of claim 22, wherein the frames are positioned within an interior of the graft.

Claim 32 (previously presented): The graft assembly of claim 22, wherein a plurality of apices of certain frames extend beyond the length of the graft.

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